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**OCT 17 2006**

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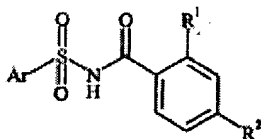
ELI LILLY AND COMPANY  
 PATENT DIVISION  
 P. O. BOX 6288  
 INDIANAPOLIS, IN 46206-6288

In re Application of	:
Mary M. Mader et al	:
Serial No.: 10/535,002	: PETITION DECISION
Filed: May 12, 2005	:
Attorney Docket No.: X-16114	:

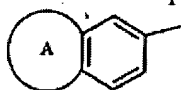
This is in response to the petition under 37 CFR 1.144, filed August 2, 2006, requesting withdrawal of an improper Lack of Unity requirement.

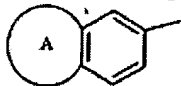
## BACKGROUND

A review of the file history shows that this application was filed under 35 U.S.C. 371 and was accepted on May 12, 2005, and contained claims 1-5. In a first Office action, mailed May 16, 2006, the examiner set forth a Lack of Unity requirement based on Formula 1, as follows:



Formula 1:

Group I, claims 1-3 and 5, drawn to compounds of Formula 1 with Ar defined as , and A is phenyl, cyclopentadienyl, cyclobutyl or cyclopentyl;

Group II, claims 1-3 and 5, drawn to compounds of Formula 1 with Ar defined as , and A is benzofuryl;

Group III, claims 1-3 and 5, drawn to compounds of Formula 1 where Ar is benzothien-2-yl, benzothien-5-yl or benzothien-6-yl;

Group IV, claims 1-3 and 5, drawn to compounds of Formula 1 where Ar is thieno[3,2-b]pyridine-2-yl;

Group V, claims 1-3 and 5, drawn to compounds of Formula 1 where Ar is 1-(C<sub>1-6</sub> alkyl)indol-2-yl; and

Group VI, claim 4, drawn to a method of use of the compounds of claim 1.

The examiner cautioned that the above list was not exhaustive and allowed applicants to elect an invention different from those listed. (The listing failed to include the benzodioxins, benzodioxols, indolinyls, benzothiazolyls and benzofuryls.) The examiner reasoned that Unity of Invention was lacking inasmuch as the structure of Formula 1 did not define over the prior art (see e.g. 6,235,680). Also, that the compounds are differently classified and result in vastly different searches. The examiner advised of the possibility of rejoinder of the method of making claims if compound claims were elected and found allowable.

Applicants replied on June 16, 2006, electing, with traverse, Group III. Applicants argued that the Lack of Unity set forth did not follow the guidelines set forth in the PCT Rules and requested that it be withdrawn. Applicants alleged that the examiner failed to properly determine the special technical feature under the PCT Markush group guidelines. Further that the method of use claims should have been considered with the composition/compound claims in accordance with PCT guidelines.

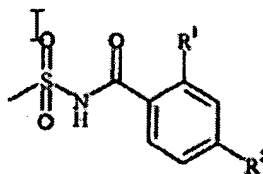
In the next Office action mailed to applicants on July 14, 2006, the examiner maintained the Lack of Unity requirement for the reasons set forth, again stating that there was no special technical feature which defined over the prior art, but did not make it Final. Also that the Ar variable controls classification and each variable it represents is classified differently. The examiner then indicated that the compounds defined by elected Group III were allowable over the prior art and that Claim 4 would not be rejoined as it was drawn to non-elected subject matter.

Applicants filed this petition on August 2, 2006, basically repeating the arguments presented to the examiner.

## DISCUSSION

Although the Lack of Unity requirement has not been made Final, it has been repeated by the examiner and the petition is properly filed.

Applicants argue that the examiner has failed to properly follow PCT guidelines in determining Lack of Unity by failing to determine the proper significant structural element. Applicants state that all of the claims are directed to compounds having as a core structure a 2,4-disubstituted benzoylsulfonamide, as shown here:



As shown, this differs from Formula 1 above only in lacking the Ar group and is found in all of the compounds, as stated by applicants. Applicants also quote the PCT guidelines for determining Unity of invention for Markush Groups, which are:

- (f)(i) When the Markush grouping is for alternatives of chemical compounds, they shall be regarded as being of a similar nature where the following criteria are fulfilled:
  - (A) all alternatives have a common property or activity, and
  - (B)(1) a common structure is present, i.e., a significant structural element is shared by all of the alternatives, or
  - (B)(2) in cases where the common structure cannot be the unifying criteria, all alternatives belong to a recognized class of chemical compounds in the art to which the invention pertains.
- (ii) In paragraph (f)(i)(B)(1), above, the words "significant structural element is shared by all of the alternatives" refer to cases where the compounds share a common chemical structure which occupies a large portion of their structures, or in case the compounds have in common only a small portion of their structures, the commonly shared structure constitutes a structurally distinctive portion in view of existing prior art, and the common structure is essential to the common property or activity. The structural element may be a single component or a combination of individual components linked together.
- (iii) In paragraph (f)(i)(B)(2), above, the words "recognized class of chemical compounds" mean that there is an expectation from the knowledge in the art that members of the class will behave in the same way in the context of the claimed invention. In other words, each member could be substituted one for the other, with the expectation that the same intended result would be achieved.
- (iv) The fact that the alternatives of a Markush grouping can be differently classified shall not, taken alone, be considered to be justification for a finding of a lack of unity of invention.
- (v) When dealing with alternatives, if it can be shown that at least one Markush alternative is not novel over the prior art, the question of unity of invention shall be reconsidered by the examiner. Reconsideration does not necessarily imply that an objection of lack of unity shall be raised.

In this particular instance the benzoylsulfonamide group could be considered to constitute the significant structural element as it does occupy a large portion of the compound structure. However, this group is extremely well known and appears in many prior art references as the basis of sulfa drugs, etc., or as a significant structural element to which some type of group is attached in the Ar position. Thus it does not itself make a contribution over the prior art, but as noted above is not required to do so. Further, consideration of what Ar can be – a fused heterocyclic or non-heterocyclic structure – shows that it would be nearly as large as the benzoylsulfonamide common structure. Additionally, as applicants assert that the compounds have a common activity, it devolves that that activity must be associated with the common core or structure, which, as has been noted above, is extremely well known. However, there appears to be no indication that benzoylsulfonamides possess the antitumor activity claimed herein in the prior art which leads to the presumption that the activity is provided by the Ar substituents. In view of this conclusion Lack of Unity does exist between the different Ar groups attached to the benzoylsulfonamide structure.

Applicants' arguments with respect to the examiner's arguments regarding different classifications and search requirements are accepted. However they are not sufficient to overcome the above presumption that the common property or activity asserted lies in the Ar substituent, not the benzoylsulfonamide common structure.

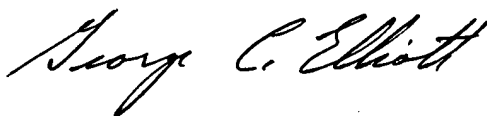
The examiner has indicated potential rejoinder of the method claim of Group VI with allowed claims. Such rejoinder is now appropriate for the compounds of elected Group III which appear to have been indicated as allowable.

## DECISION

The petition is **GRANTED-IN-PART**. The restriction requirement between Groups I-V is maintained. Group VI (claim 4) will be rejoined with the elected compounds of Group III.

**Applicants remain under obligation to reply to the Office action of July 14, 2006, within the time period set therein, or as extended under 37 CFR 1.136(a).**

Should there be any questions about this decision please contact William R. Dixon, Jr., by letter addressed to Director, TC 1600, at the address listed above, or by telephone at 571-272-0519 or by facsimile sent to the general Office facsimile number, 571-273-8300.

A handwritten signature in cursive script, reading "George C. Elliott".

George C. Elliott  
Director, Technology Center 1600